

### AMENDMENTS TO THE CLAIMS

Please amend the claims as follows:

1. (Withdrawn) A rotary blood pump for use in a heart assist device of like device, said pump having an impeller suspended in use within a pump housing by hydrodynamic thrust forces generated by relative movement of said impeller with respect to and within said pump housing; and wherein at least one of said impeller or said housing includes at least a first deformed surface lying on at least part of a first face which, in use, moves relative to respective facing surfaces on the other of said impeller or said housing thereby to form a relatively moving surface pair which generates relative hydrodynamic thrust between said impeller and said housing which includes everywhere a localized thrust component substantially and everywhere normal to the plane of said first deformed surface.

2. (Previously presented) A rotary blood pump for use in a heart assist device, said pump having an impeller suspended in use within a pump housing by hydrodynamic thrust forces generated by relative movement of said impeller with respect to and within said pump housing; and wherein at least one of said impeller or said housing includes at least a first deformed surface lying on at least part of a first face which, in use, moves relative to respective facing surfaces on the other of said impeller or said housing thereby to form a relatively moving surface pair which generates relative hydrodynamic thrust between said impeller and said housing which includes everywhere a localized thrust component substantially and everywhere normal to the surface of said first deformed surface.

3. (Previously presented) The pump of Claim 2, wherein the pump includes a hydrodynamic bearing.

4. (Previously presented) The pump of Claim 2, wherein said pump includes radial and axial direction control and said radial and axial direction control is provided by the inclusion of one set of surfaces angled with respect to the rotational axis of the impeller.

5. (Previously presented) The pump of Claim 2, wherein said impeller includes blades which are tapered or non-planar, so that a thrust is created between the edges and the pump housing during relative movement therebetween.

6. (Previously presented) The blood pump of Claim 2, wherein said pump is of centrifugal type or mixed flow configuration; and the blades form gaps in said impeller; wherein said gaps open on both front and back faces of the impeller.

7. (Previously presented) The pump of Claim 6, wherein the front face of the pump housing is generally conical shaped, to allow thrust forces to be generated generally perpendicular to an inner conical surface of the housing and wherein said thrust forces have a radial component to resist radial displacement of the impeller axis, in use.

8. (Previously presented) The pump of Claim 2, wherein a drive torque of said impeller derives from the magnetic interaction between permanent magnets within the blades of the impeller and oscillating currents in windings encapsulated within the pump housing.

9. (Previously presented) The pump of Claim 8, wherein said pump is of an axial configuration.

10. (Previously presented) The pump of Claim 9, wherein said impeller includes tapered blade edges which form a radial hydrodynamic bearing.

11. (Previously presented) The pump of Claim 10, wherein an interior of the pump housing is constructed with a reducing radius at least one end, and wherein said end experiences thrust forces generated by impeller cooperating with the housing and said thrust forces have an axial component.

12. (Previously presented) The pump of Claim 11, wherein magnetic forces provide the axial bearing.

13. (Previously presented) The pump of Claim 2, wherein the distance between the surfaces of said relatively moving surface pair is less than 0.2 mm.

14. (Previously presented) The pump of Claim 2, wherein the distance between the surfaces of said relatively moving surface pair is less than 0.1 mm.

15. (Previously presented) The pump of Claim 2, wherein said first deformed surface forms of and is integral to at least one surface of said impeller.

16. (Currently amended) A rotary blood pump for assisting blood circulation comprising: a plastic, metal or ceramic housing; ~~an~~ a hydrodynamically suspended impeller wherein said impeller, in use, is magnetically urged to rotate; and at least one stator assembly.

17. (Previously presented) The pump of Claim 16, wherein at least a portion of said pump is coated with a biocompatible film.

18. (Previously presented) The pump of Claim 17, wherein said film includes titanium nitride or carbon.

19. (Canceled).

20. (Previously presented) The pump of Claim 19, wherein said impeller includes at least one blade.

21. (Previously presented) An implantable rotary blood pump comprising: a housing; an impeller where said impeller, in use, is magnetically urged to rotate; a hydrodynamic bearing formed by the cooperation of a surface of said impeller and said housing; and at least one stator assembly.

22. (Previously presented) A rotary blood pump comprising: a housing, at least one stator assembly, and a hydrodynamically suspended impeller; wherein said impeller carries at least one permanent magnet; and wherein said magnet produces an axis of magnetism and wherein said axis of magnetism is offset at an angle extending away from the axis of rotation of said impeller.

23. (Previously presented) A rotary blood pump comprising: a polymeric housing, a hydrodynamically suspended impeller wherein said impeller, in use, is magnetically urged to rotate; and at least one stator assembly.

24. (Previously presented) A rotary blood pump comprising: a housing; a casing, a hydrodynamically suspended impeller wherein said impeller, in use, is magnetically urged to rotate; at least one stator assembly and wherein said stator assembly and impeller cooperate to form a three phase motor.

25. (Previously presented) A shaftless rotary blood pump comprising: a housing; a casing, a hydrodynamically suspended impeller wherein said impeller is magnetically urged to rotate; and at least one stator assembly.

26. (Previously presented) A rotary blood pump comprising: a housing, a hydrodynamically suspended impeller wherein said impeller, in use, is magnetically urged to rotate, at least two stator assemblies wherein at least a portion of one said stator assembly is aligned at generally 45° to an axis of rotation of the said impeller.

27. (Previously presented) A rotary blood pump comprising: a housing a hydrodynamically suspended impeller wherein said impeller, in use, is magnetically urged to rotate; at least one stator assembly and, in use, movement of impeller generates axial and/or radial thrust forces.

28. (Previously presented) A rotary blood pump comprising: a housing, a impeller wherein said impeller includes an integral hydrodynamic bearing surface and, in use, said impeller is magnetically urged to rotate; and at least one stator assembly.

29. (Previously presented) A blood pump for assisting blood circulation comprising: a housing a hydrodynamically suspended impeller wherein said impeller, in use, is magnetically urged to rotate; and at least one stator assembly.

30. (Previously presented) The pump of Claim 29, wherein said pump is shaftless.

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31. (Previously presented) The pump of Claim 30, wherein said impeller includes at least two blades.

32. (Previously presented) The pump of Claim 31, wherein said blades are supported by at least one support cone.

33. (Previously presented) The pump of Claim 32, wherein said support cone generates a partial bearing means by the generation of hydrodynamic thrust forces, in use.

## REMARKS

In the Office Action mailed May 20, 2004, the Examiner rejected claims 2-7 and 15-33 under 35 USC §§ 102(e) and 103(a). The Examiner also stated that claims 8-14 are allowable, but are objected to as being dependent upon a rejected claim. By this paper, Applicant addresses each of the Examiner's rejections and objection.

### Rejection of Independent Claims Under 35 USC § 102(e) based on Nakazeki

The Examiner rejected independent claims 2, 21, 22, 25, and 27 under 35 USC § 102(e) by citing the Nakazeki et al. reference (U.S. Patent No. 5,725,357). In particular, the Examiner stated that the Nakazeki reference discloses "a hydrodynamically suspended impeller 22." After reviewing the Nakazeki reference, Applicant respectfully submits that such a statement is incorrect for the following reasons.

Applicant believes that the Nakazeki reference teaches (e.g., in the Abstract) a device relating to a "magnetically suspended type pump," meaning the impeller is suspended by magnetic forces acting upon the impeller rather than hydrodynamic forces as claimed in each of the independent claims of the present Application. By this paper, Applicant has amended independent claim 16 to include the "hydrodynamically suspended" limitation for the impeller.

Applicant further notes that the Nakazeki reference also states that "in the magnetically suspended type pump structured as described above, permanent magnet 14 embedded in rotor 12 supports the radial direction and driving of impeller 22 and produces axial attraction between the permanent magnet 14 itself and permanent magnet 24 provided in impeller 22. Current is applied to a coil of electromagnet 31 so as to balance with this attraction, and impeller 22 is suspended" (beginning at column 3, line 54). Applicant believes that such disclosure demonstrates that the suspension of the rotor and impeller in the Nakazeki reference teaches magnetic suspension and not hydrodynamic suspension as claimed in the present Application.

Applicant notes that hydrodynamic suspension of the impeller is advantageous because less power is required by the pump to operate than that of a comparable magnetic suspension type; and thereby a pump having the hydrodynamically suspended impeller is generally more efficient in terms of power usage.

The Examiner further states about the Nakazeki reference that “permanent magnet 24 is in impeller 22 and permanent magnet 14 in rotor 12 supports the radial direction and driving of impeller 22.” This it appears that the Examiner sees the impeller as being supported radially and axially by magnetic forces. Such a feature further suggests that the suspension of the pump disclosed in the Nakazeki reference is entirely magnetic.

Applicant further notes that the Nakazeki reference (in the description of Figures 11A and B, column 6, line 34) discloses that the “impeller 22 is passively supported by this magnetic coupling. An electromagnet 31 is provided on the side of circular plate 223 as a control type magnetic bearing, and the axial direction of the impeller 22, rotor 12 is rotated when driven by the motor 13 and transmits driving force to impeller 22 by the magnetic coupling.” Such a feature further suggests that the suspension of the pump disclosed in the Nakazeki reference is entirely magnetic.

Applicant further notes that Nakazeki reference (in the description of Figure 14A, column 8, line 18) describes how the impeller is suspended by a pivot bearing: “a pivot bearing is put on the center of circular plate 221, and supports impeller 220 by coming in contact with the case.” Applicant submits that nothing in the Nakazeki reference discloses, suggests, or anticipates the hydrodynamically suspended impeller feature as claimed in the present Application.

For the foregoing reasons, Applicant submits that the independent claims of the present Application are patentable over the Nakazeki reference.

#### Rejection of Independent Claims Under 35 USC § 102(e) based on Khanwilkar

The Examiner rejected independent claims 24 and 26 under 35 USC § 102(e) by citing the Khanwilkar et al. reference (U.S. Patent No. 6,074,180). In particular, the Examiner stated that the Khanwilkar reference discloses “a hydrodynamically suspended impeller 21 and a three phase brushless DC motor 40.” After reviewing the Khanwilkar reference, Applicant respectfully submits that it does not disclose a hydrodynamically suspended impeller, but rather a magnetically suspended impeller, for the following reasons.

Applicant believes that the Khanwilkar reference teaches (e.g., in the Abstract) a device relating to a “an apparatus and method for a centrifugal fluid pump ....., which includes (i) an integral impeller and rotor which is entirely supported by an integral combination of permanent

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magnets and electromagnetic bearings and rotated by an integral motor,” meaning the impeller is entirely suspended, in use, by magnetic forces acting on the impeller and/or the rotor.

Applicant notes that the Khanwilkar reference states “[t]he pump impeller is magnetically suspended with a combination of permanent magnets and electromagnetic bearing” (column 8, line 23). There is no hydrodynamic bearing attached to the impeller disclosed in the Khanwilkar reference.

With respect to claim 26 of the present Application, Applicant notes that the claim includes a limitation of “at least a portion of one stator assembly is aligned at generally 45° to an axis of rotation of said impeller.” Applicant believes that such a feature is not disclosed, suggested, or shown in the Khanwilkar reference. All of the accompanying figures of the Khanwilkar reference show stator assemblies that are generally parallel to the axis of rotation of the impeller. The angulation of the stator assemblies in the present Application may assist the functioning of hydrodynamically suspended impeller.

For the foregoing reasons, Applicant submits that the independent claims of the present Application are patentable over the Khanwilkar reference.

#### Rejection of Independent Claims Under 35 USC § 103(a)

The Examiner rejected independent claims 16 and 23 under 35 USC § 103(a) as being unpatentable over the Khanwilkar reference in view of the Nose et al. reference (U.S. Patent No. 5,713,730). In particular, the Examiner stated that “[u]sing the teaching of Nose et al one of ordinary skill in the art would have found it obvious to form the housing of Khanwilkar et al of ceramic and coat it using a biocompatible film.” After reviewing the Khanwilkar and Nose references, Applicant respectfully submits that such a combination is not obvious for the following reasons.

Applicant notes that neither Khanwilkar nor Nose discloses a hydrodynamically suspended impeller or hydrodynamic bearings attached to the impeller. Thus, the combination of these two references does not teach, suggest, anticipate, or make obvious any of the claims of the present Application.

Applicant further notes that the Nose reference describes a centrifugal blood pump with an impeller, casing and drive outside the casing. For example, the abstract of the Nose reference



states that “the impeller may have pivots integrated at opposite ends for allowing the impeller to rotate about a horizontal axis. The pivots may be supported by pivot bearings disposed within the casing.” Applicant believes that such a description means that the impeller is suspended by mechanical pivots attached to impeller and not by hydrodynamic suspension.

Applicant further notes that the Nose reference discloses that “[t]he impeller is supported by a bearing at the end of the impeller’s rotation center at least on the rotary vane section side .... The end of the impeller’s rotation center on the rotary vane section side is supported by a pivot and a pivot bearing.” (column 4, line 13). There is nothing in the Nose reference that teaches or suggests the feature of a hydrodynamically suspended impeller.

Applicant further notes that the Nose reference discloses a pivot bearings made from ceramic materials. Based on the disclosure of the Nose reference, Applicant believes that the only ceramic components are said pivot bearings. In contrast, the claimed device of the present Application may not need to have a pivot bearing as they are replaced with a hydrodynamic bearing. Therefore, the use of materials such as plastic, metal or ceramic in the housing is not obvious.

For the foregoing reasons, Applicant submits that the independent claims of the present Application are patentable over the Khanwilkar and Nose references.

#### Rejection of and Objection to Dependent Claims

The Examiner rejected various dependent claims as being unpatentable over the Nakazeki, Khanwilkar and/or Nose references. The Examiner also objected to otherwise allowable dependent claims 8-14 for depending from rejected claims. These dependent claims include limitations in addition to all of the limitations of their respective base claims. For reasons stated above, Applicant submits that the independent claims are patentable over the cited references. Thus, Applicant submits that these dependent claims are also patentable over the cited references.